IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MATTHEW W. HALL and MICHAEL F. CAREY, **Plaintiffs,** **v.** **ABINGTON MEMORIAL HOSPITAL, d/b/a ABINGTON HOSPITAL-JEFFERSON HEALTH,** **Defendant.**	**CIVIL ACTION NO. 22-2429**

Scott, J. **September 22, 2023**

MEMORANDUM

Plaintiffs Matthew Hall and Michael Carey allege that Defendant Abington Memorial Hospital, d/b/a Abington Hospital-Jefferson Health (Abington), wrongfully terminated them in retaliation against their attempts to pressure Abington's Sleep Disorders Center (the Sleep Center) to stop using machines that had been recalled by the United States Food and Drug Administration (FDA). The plaintiffs claim that Abington's termination of them violated the retaliation provision of the False Claims Act (FCA), 31 U.S.C. § 3730(h), the Pennsylvania Whistleblower Law, 43 P.S. §§ 1421-28, and Pennsylvania common law's public policy against wrongful discharge. Although Abington claims that the plaintiffs were terminated for unrelated lawful reasons, the plaintiffs contest that those reasons were merely pretext for unlawful retaliation. Abington has moved to dismiss the plaintiffs' claims. Abington's motion to dismiss will be granted, because the complaint fails to plausibly allege that Mr. Hall's and Mr. Carey's efforts were protected activities under the FCA's retaliation provision. Because the plaintiffs' sole federal claims are their FCA retaliation claims, the court declines to exercise supplemental jurisdiction over the plaintiffs' state law claims.

I. BACKGROUND

Mr. Hall worked for Abington for over 15 years, and Mr. Carey worked for Abington for over 25 years. *See* Compl. ¶ 15, ECF No. 1. Both plaintiffs worked as polysomnographers or sleep technicians in the Sleep Center, where they were directly supervised by Scott McMaster, Associate Director of the Neurosciences Institute. *Id.* at ¶¶ 14, 17.

In June 2021, the plaintiffs learned from Mr. McMaster or a physician in the Sleep Center that at least some of the machines used in the Sleep Center had been recalled. *Id.* at ¶ 18. According to the FDA's website, in June 2021, Philips Respironics voluntarily recalled certain ventilators, bi-level positive airway pressure (also known as BiPAP or BPAP) machines, and continuous positive airway pressure (CPAP) machines (the recalled Philips machines). *Id.* at ¶ 19. The Philips machines were recalled because foam used in the machines could break down, causing users to inhale or swallow foam or chemicals. *See id.* In July 2021, the FDA classified the recall of the Philips CPAP machines as a Class 1 recall, which means that use of the recalled unit could cause serious injury or death. *See id.* at ¶ 24.

Allegedly, the Sleep Center briefly stopped using the recalled units, but then began to use them again by early July 2021. *Id.* at ¶¶ 20-21. Immediately after that, Mr. Hall and Mr. Carey began complaining to Mr. McMaster about the continued use of the Philips machines. *Id.* at ¶ 22. Mr. McMaster responded that treatment using the recalled machines was better than no treatment at all. *Id.* at ¶ 23. At some point, Mr. McMaster allegedly directed the plaintiffs "to lie to patients by falsely reassuring them that using recalled units was safe." *Id.* at ¶ 31. Finally, on or around March 4, 2022, Mr. Hall and Mr. Carey brought their complaints to Dr. Richard E. Friedenheim, Medical Director of the Sleep Center. *Id.* at ¶ 25. The plaintiffs reported to Dr. Friedenheim that they had complained to Mr. McMaster for months and felt uncomfortable using the recalled

Philips machines. *Id.* at ¶ 26. Dr. Friedenheim responded that he believed that Mr. McMaster had already replaced the recalled units, and he directed Mr. Hall and Mr. Carey to speak with Mr. McMaster. *Id.* at ¶ 27.

After this meeting, Mr. Hall and Mr. Carey approached Mr. McMaster in the hallway outside of Dr. Friedenheim's office. *Id.* at ¶ 29. They told Mr. McMaster that it was unethical to put patients' safety at risk and that they were uncomfortable with lying to patients about the machines' safety. They then asked, "What do we have to do to get working equipment, go to OSHA?" *Id.* at ¶¶ 29-30.

On March 10, 2022—less than one week later—Mr. McMaster and two Human Resources representatives informed Mr. Hall and Mr. Carey that they would be suspended without pay for three reasons: (1) they had left a patient unattended, (2) they had used a cart of cleaning supplies that was now missing, and (3) they had left a shift for two to three hours. *Id.* at ¶ 32. Mr. Hall and Mr. Carey dispute these events, arguing that (1) the allegation of leaving a patient unattended was vague, (2) they had used the cleaning supplies to clean patients' rooms after obtaining the housekeeping team's permission to use the cart, and (3) Mr. McMaster knew or should have known that they left their shift that day to travel to Abington's other Sleep Center site to look for machines to use that had not been recalled. *Id.*

On March 31, 2022, Mr. Hall and Mr. Carey were informed that they were terminated effective April 1, 2022, due to their violations of Abington's policies. *Id.* at ¶¶ 34-35. Mr. Hall and Mr. Carey allege that they had had no other disciplinary issues in the 15 years before their terminations. *Id.* at ¶ 37. The complaint also alleges that Abington replaced several of the recalled Philips machines on or about the same day that Abington terminated Mr. Hall and Mr. Carey.

On June 21, 2022, Mr. Hall and Mr. Carey filed the instant complaint, which asserts that Abington's termination of the plaintiffs was unlawful retaliation against their efforts to replace the recalled Philips machines that violated both the FCA's retaliation provision and the Pennsylvania Whistleblower Law. *See id.* at ¶¶ 51-66. The complaint also asserts that the termination was a wrongful discharge that violates public policy, citing Pennsylvania state law that requires the provision of safe outpatient services and working medical equipment and that mandates that health care workers report serious events or incidents that jeopardize patient safety. *See id.* at ¶¶ 67-72.

Abington moved to dismiss all of the complaint's claims on September 29, 2022. *See* Mot. to Dismiss, ECF No. 11. The plaintiffs filed a brief opposing the motion to dismiss on October 26, 2022. *See* Pls.' Br. in Opp'n to Def.'s Mot. to Dismiss, ECF. No. 14 (Pls.' Resp.). Abington filed a reply brief on November 9, 2022. *See* Def.'s Unopposed Mot. for Leave to File Reply Br., ECF No. 15 (Def.'s Reply); Order, Nov. 9, 2022, ECF No. 16. This matter was reassigned from the Honorable Mitchell S. Goldberg to this court on February 27, 2023.

II. LEGAL STANDARDS

A complaint survives a motion to dismiss if it contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). District courts in the Third Circuit use a three-step process to evaluate a motion to dismiss a complaint for failure to state a claim for relief. *See Lutz v. Portfolio Recovery Associates*, LLC, 49 F.4th 323, 327 (3d Cir. 2022) (relying on framework established in *Connelly v. Lane Constr. Corp.*, 809 F.3d 780, 787-90 (3d Cir. 2016) and *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009)). First, the court articulates the elements of the claims raised. *See id.* Second, the court

reviews the complaint and disregards any allegations that are merely conclusory or formulaic recitations of the elements of the claim or that are "so threadbare or speculative that they fail to cross the line between the conclusory and the factual." *See id*. at 327-28 (internal citations omitted). Third, the court considers whether the remaining allegations plausibly entitle the plaintiff to relief. *See id*. at 328. To do so, the court must assume that all well-pleaded factual allegations are true, construe the allegations in the light most favorable to the plaintiff, and draw all reasonable inferences in the plaintiff's favor. *See id.* The plausibility standard does not require the complaint to establish a probability of relief or to demonstrate that all prima facie elements of a claim can be met. *See Ashcroft*, 556 U.S. at 678; *Fowler*, 578 F.3d at 210-11. Instead, a complaint plausibly pleads a claim if it raises "more than a sheer possibility that a defendant has acted unlawfully," *Ashcroft*, 556 U.S. at 678, or a "reasonable expectation that discovery will reveal evidence of the necessary elements of a claim." *Lutz*, 49 F.4th at 328 (internal quotations omitted).

Generally, a district court evaluating a motion to dismiss can consider only the complaint's allegations, any exhibits attached to the complaint, and matters of public record; if the court exceeds those constraints, the motion to dismiss is converted into a motion for summary judgment. *See Schmidt v. Skolas*, 770 F.3d 241 (3d Cir. 2014) (citations omitted). However, a district court may properly consider documents that are "integral to or explicitly relied upon in the complaint" without converting the motion to dismiss into a motion for summary judgment. *See id.* (language deemphasized and internal citation omitted).

III. DISCUSSION

A. Overview of the FCA and its Protections from Retaliation

The FCA prohibits any person from knowingly presenting "a false or fraudulent claim for payment or approval" to the United States government. 31 U.S.C. § 3729 (a)(1)(A). The FCA also protects employees (and some other actors) from retaliation against certain whistleblowing activities. 31 U.S.C. § 3730(h)(1). A plaintiff proves a claim of FCA retaliation by showing that he (1) "engaged in protected conduct" and (2) "was discriminated against because of his protected conduct." *See United States ex rel. Ascolese v. Shoemaker Construction Co.* (*Ascolese*), 55 F.4th 188, 191, 194 (3d Cir. 2022);[1] *DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 76 (3d Cir. 2018). The FCA enumerates two types of protected activities: (1) "lawful acts done . . . in furtherance of an [FCA] action" and (2) "other efforts to stop 1 or more violations of [the FCA]". 31 U.S.C. § 3730(h)(1). The Third Circuit has referred to these activities as the "FCA litigation" prong and the "other efforts" prong, respectively, and it has recently emphasized that Congress's addition of the "other efforts" prong through 2009 and 2010 amendments reflects Congress's intent to expand FCA's anti-retaliation protections. *See Ascolese*, 55 F.4th at 191, 194.

The Third Circuit has not yet adopted a test for ascertaining what constitutes "other efforts to stop 1 or more violations of [the FCA]."[2] Several other circuit courts have not adopted

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[1] *Ascolese* was filed on November 30, 2022, after the parties had fully briefed this motion to dismiss. However, *Ascolese* reiterated the same prima facie elements of a FCA retaliation claim that the Third Circuit has applied since at least 2001. *See Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 186 (3d Cir. 2001).

[2] The Third Circuit has applied a "distinct possibility" standard to retaliation claims under the "FCA litigation" prong. *Ascolese*, 55 F.4th at 191. The distinct possibility standard requires a plaintiff to demonstrate that their employer "had notice of the distinct possibility that the plaintiff was contemplating the filing of an FCA lawsuit." *Id.* (citing *Hutchins*, 253 F.3d at 179). But the *Ascolese* Court clarified that the distinct possibility standard does not apply to retaliation claims raised under the "other acts" prong. *See id.* at 194-95 (distinguishing *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497 (3d Cir.

a specific test but have required at least some nexus between the plaintiff's actions and an FCA violation. *See, e.g.*, *United States ex rel. Reed v. KeyPoint Gov't Solutions*, 923 F.3d 729, 767 (10th Cir. 2019) ("a relator's actions still must convey a connection to the [FCA]"); *Hickman v. Spirit of Athens, Alabama, Inc.*, 985 F.3d 1284, 1288-89 (11th Cir. 2021) (plaintiffs "are, at a minimum, required to show that the activity they were fired over had *something* to do with the False Claims Act–or at least that a reasonable person might have thought so"). The Eleventh Circuit's reasoning is particularly persuasive:

> An organization might commit, and its employees might believe it has committed, any number of legal or ethical violations–but the [FCA's] retaliation provision only protects employees where the suspected misdeeds are a violation of *the False Claims Act*, not just of general principles of ethics and fair dealing. It is not enough for an employee to suspect fraud; it is not even enough to suspect misuse of federal funds. In order to file under the [FCA], whether in a qui tam or a retaliation action, an employee must suspect that her employer has made a false claim to the federal government.

Hickman, 985 F.3d at 1289 (emphasis in original). This aligns with the general principle that the FCA is not merely an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. United States ex rel. Escobar* (*Escobar*), 579 U.S. 176, 194 (2016).

Several circuits have developed more specific tests that require the district court to apply an "objective reasonableness" analysis. Under an objective reasonableness standard,

> an act constitutes protected activity where it is motivated by an objectively reasonable belief that the employer is violating, or soon will violate, the FCA. A belief is objectively reasonable when the plaintiff alleges facts sufficient to show that he believed his employer was violating the FCA, that this belief was reasonable, that he took action based on that belief, and that his actions were designed to stop one or more violations of the FCA. However, while the plaintiff's actions need not 'lead to a viable FCA action' as required under the distinct possibility standard, they must still have a nexus to an FCA violation.

2017)). However, the Third Circuit did not adopt a more specific standard in *Ascolese* of what constitutes "other efforts to stop 1 or more" FCA violations.

United States ex rel. Grant v. United Airlines, 912 F.3d 190, 201-02 (4th Cir. 2018). In addition to the Fourth Circuit, the D.C. Circuit, Second Circuit, Seventh Circuit, Eighth Circuit, and Ninth Circuit have implicitly approved of or explicitly adopted similar objective reasonableness tests.[3]

In sum, as the Third Circuit cautioned in *Ascolese*, it is inappropriate to require a plaintiff raising an "other acts" retaliation claim to show that the plaintiff put their employer on notice of a "distinct possibility" that the plaintiff could or would pursue FCA litigation. Because the Third Circuit has not yet adopted a test for determining what constitutes "other acts," it is necessary to look to other circuits for persuasive guidance. Circuits that have reached the issue have clarified that plaintiffs raising an "other acts" retaliation claim must demonstrate that some nexus exists between their actions and the prevention of an actual or potential violation of the FCA. Additionally, the objective reasonableness standard approved in several circuits can be applied as a workable, practical aid in determining whether a plaintiff has engaged in efforts to prevent one or more violations of the FCA.

The second element of a FCA retaliation claim requires plaintiffs to show that they were discriminated against "because of" their protected conduct. Plaintiffs must demonstrate that the discrimination would not have occurred but for the plaintiffs' protected activity; the protected activity cannot merely be one of several motivating factors that lead to discriminatory treatment. *See DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 76-78 (3d Cir. 2018).

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[3] *See, e.g.*, *Singletary v. Howard Univ.*, 939 F.3d 287, 296 (D.C. Cir. 2019) (the "other efforts" prong "requires that the employee's efforts pertain to fraud in connection with the submission of a claim for federal government funds. But that test is met as long as the employee has an objectively reasonable belief that the employer is violating, or will violate, the [FCA]"); *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 96 (2d Cir. 2017); *U.S. ex rel. Uhlig v. Fluor Corp.*, 839 F.3d 628, 635 (7th Cir. 2016); *U.S. ex rel. Strubbe v. Crawford Co. Mem'l Hosp.*, 915 F.3d 1159, 1167 (8th Cir. 2019); *U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 908 (9th Cir. 2017).

Finally, it is important to emphasize that plaintiffs who raise FCA retaliation claims are not required to point to some explicit contractual provision that a defendant has violated or could potentially violate. The United States Supreme Court has unanimously endorsed an "implied false certification theory," which requires showing that the "defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 181. In *Escobar*, the Court emphasized that it does not matter whether the federal government expressly designated a requirement as a condition of its payment for goods or services; what matters is "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *See id*. At least two conditions must be satisfied for the implied certification theory to provide a basis for liability: "[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 190.

In adopting this test, the Supreme Court rejected "a circumscribed view of what it means for a claim to be false or fraudulent," in part because a strict application of the FCA's materiality requirement could address any concerns about fair notice to the defendant or open-ended liability. *See id.* at 192. *Escobar* emphasized that the FCA's "materiality standard is demanding": Even if the government has required compliance with a specific statutory, regulatory, or contractual provision, it does not automatically follow that noncompliance with that provision is material to the government's payment decision. In light of *Escobar*, the Third Circuit has emphasized that "[a] materiality inquiry under the FCA is a holistic, totality-of-the-

circumstances examination of whether the false statement has 'a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *United States ex rel. Int'l Brotherhood of Electrical Workers Local Union No. 98 v. The Fairfield Co.*, 5 F.4th 315, 342 (3d Cir. 2021) (quoting 31 U.S.C. § 3729 (b)(4)).

B. The Plaintiffs Do Not Plausibly Plead that They Engaged in Activity that is Protected Under the FCA's Retaliation Provision

Here, the complaint fails to articulate how the plaintiffs' efforts to replace the recalled Philips machines could have prevented Abington from submitting false or fraudulent claims to Centers for Medicare and Medicaid Services (CMS) or to any other part of the federal government.

The complaint's FCA claim is not very detailed, but the complaint at least pleads that (1) the Sleep Center conducted multiple sleep studies on patients every day, (2) each sleep study costs about $6,000 to $8,000, and (3) many of the Sleep Center's patients received coverage from Medicare or Medicaid for sleep studies. *See* Compl. ¶¶ 38-39. The complaint implicitly argues that a reimbursement claim submitted by Abington to CMS for a sleep study conducted using a recalled Philips machine is a false or fraudulent claim that violates the FCA. *See id.* at ¶¶ 38-43. The complaint further alleges that no Sleep Center employee informed patients of the recall or helped patients weigh the risks and benefits of using the recalled Philips machines. *See id.* at ¶ 40. Mr. Hall and Mr. Carey allege that their complaints to Mr. McMaster and Dr. Friedenheim were "about patient safety and compliance issues . . . These complaints dealt with gross [mismanagement] of a federal contract or grant, gross waste of federal funds, abuse of authority relating to a federal contract or grant, substantial and specific danger to public health or safety or violations of Medicare or Medicaid." *Id.* at ¶ 41. However, these are conclusions rather than factual allegations or logical inferences.

A Medicare or Medicaid reimbursement claim qualifies as a "claim" under the FCA. *See*, *e.g.*, *Escobar*, 579 U.S. at 183; *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486-87 (3d Cir. 2017) (*Petratos*). But the complaint fails to explain how Abington's use of a recalled Philips machine during a sleep study would render a claim made to CMS for the sleep study fraudulent. The complaint does not identify an express violation of an FDA or CMS regulation or contract. Nor does it forward an implied false certification theory.

First, the plaintiffs have not cited any document that shows that Abington violated any *express* rule or regulation set forth by the FDA by continuing to use the recalled Philips machines after the recall. Specifically, the complaint quotes an FAQ webpage that the FDA compiled about the recall, but that FAQ page does not direct any healthcare facilities or professionals to discuss the recall with patients or people who use the machines. *See* Compl. ¶ 19; *See* FDA, *FAQs on Philips Respironics Ventilator, BiPAP Machine, and CPAP Machine Recalls* (last updated June 2, 2023), https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls (FDA's Recall FAQ Webpage). Instead, the FAQ page directs people to talk with their doctors if they have questions about whether they should continue to use their recalled machines, and notes that "[f]or some patients, stopping use of the recalled or repaired device may involve greater risk than continuing its use." *See* FDA's Recall FAQ Webpage. As Abington thoroughly explains, the FDA's Recall FAQ Webpage and the FDA's March 10, 2022, notification order only required *Philips* to notify patients and consumers of the recall. *See* Mot. to Dismiss 7-8, 15. These FDA publications did not require healthcare providers like Abington to communicate with patients about the recall. *See id.* Finally, the court notes that when the FDA's Recall FAQ Webpage was last updated in June 2023, Philips was *still* in the process of replacing recalled devices. *See*

FDA's Recall FAQ Webpage. Thus, the plaintiffs' cited FDA literature did not explicitly require Abington to replace the recalled Philips devices during the year that the plaintiffs protested the Sleep Center's continued use of the recalled machines.

Second, the plaintiffs have not cited any express rule or regulation forwarded by CMS that would have required Abington to stop using the recalled Philips machines prior to the plaintiffs' termination. The plaintiffs' complaint makes no reference to any CMS documents, but the plaintiffs' response to the motion to dismiss quotes information about the recall that was posted on CMS's Durable Medical Equipment Center webpage. *See* Pls.' Resp. 11-12. It is unclear when that information was posted, but it notes that the recall occurred on June 14, 2021, and that "Philips Respironics will repair or replace devices affected by this recall; it could take up to a year to complete these remediation tasks." *See Respiratory Equipment Affected by Recent Philips Respironics Recall*, https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center (last visited Sept. 5, 2023). The post states, under the heading "Supplier Responsibility," that "You must help Medicare patients who rent or own devices affected by the recall and explain which items and services are covered and paid for related to this recall." *See id.* But the complaint does not identify Abington as a *supplier* of recalled devices to patients; the complaint focuses only on the Sleep Center's *use* of the devices in its monitored sleep studies. Thus, because the CMS bulletin did not require Abington to replace the recalled Philips devices, the CMS bulletin does not support the plaintiffs' FCA claim.

Third, the complaint does not forward a cognizable implied false certification theory. The plaintiffs do not cite to *any* federal statutory, regulatory, or contractual requirement that Abington could have violated by using recalled Philips machines in sleep studies. As written, the complaint reflects the plaintiffs' concerns that the recalled machines could harm patients and

perhaps that the recalled devices were used without efforts to obtain patients' informed consent.[4] However, no connection is made between those concerns and some CMS regulation or contractual provision that Abington could have violated. The complaint alleges "gross [mismanagement] of" or "abuse of authority relating to a federal contract or grant," but these are conclusory allegations that are not supported by any citation, so the court will not credit them. Moreover, even if the court could easily identify some CMS regulation that matches these conclusory statements, the complaint fails to explain why those violations would have been material to the *government's* decision to reimburse Abington for those sleep studies. *See Petratos*, 855 F.3d at 491 ("the Government will always be the recipient of the misrepresentation in the [FCA] context").

The Third Circuit's reasoning in *Petratos* is especially instructive here. In *Petratos*, a pharmaceutical company's former employee alleged that the company had concealed and misrepresented evidence of serious side effects of Avastin (a drug designed to treat cancer) from both the FDA and prescribing doctors. *Id.* at 485. The former employee argued that these misrepresentations caused doctors to incorrectly certify that Avastin was "reasonable and necessary" [5] for certain Medicare patients; if the doctors had known of the concealed risks, they would have prescribed less Avastin or no Avastin at all to certain patients. *Id.* at 485-86. The Third Circuit reviewed CMS guidance and concluded that the "reasonable and necessary"

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[4] *See* Compl. ¶¶ 29-31, 40. The complaint does not explicitly mention a failure to obtain informed consent, but it does allege that Mr. McMaster directed Mr. Hall and Mr. Carey to "falsely reassur[e patients] that using recalled units was safe," *id.* at ¶ 31, and that Sleep Center employees failed to "review[] with the patients whether the benefit of using the recalled sleep units outweighed the risk[s]," *id.* at ¶ 40. The plaintiffs' response to Abington's motion to dismiss asserts that the failure to disclose or obtain informed consent from patients before using recalled machines is a type of fraud under the FCA, but there is no further explanation or citation to support this assertion. *See* Pls.' Resp. 15.

[5] "The Medicare statute provides that 'no payment may be made' for items and services that 'are not reasonable and necessary for the diagnosis and treatment of illness or injury.'" *Petratos*, 855 F.3d at 487 (quoting 42 U.S.C. § 1395y(a)(1)(A)).

determination does not rise and fall with FDA approval; FDA approval is just one important factor in the analysis of whether a prescribed drug is "reasonable and necessary." *See id.* at 487-88. The particular claim "must also be 'reasonable and necessary for [the] *individual patient*' based on 'accepted standards of medical practice and the medical circumstances of the *individual case*.'" *Id.* at 488 (emphasis and alterations in original). The Court held that the former employee had failed to meet the FCA's materiality standard, and explicitly rejected the arguments that (1) physicians would have prescribed less Avastin if they knew of the side effects, and thus the government would have paid fewer claims, and (2) fraudulent misrepresentations that were material to the physicians' determinations were imputed to the government. *See id.* at 490-92. The Third Circuit unequivocally instructed that the "focus here should not be whether the alleged fraud deceived the prescribing physicians, but whether it affected CMS's payment decision." *Id.* at 492. The former employee had failed to raise a viable FCA claim because he had not pleaded that CMS would have refused to reimburse claims for Avastin prescriptions or even that CMS's knowledge of the concealed side effects would have influenced CMS's payment decisions. *See id.* at 490.

Here, the complaint similarly misdirects its focus on information concealed from patients and potential patient safety issues; there is no discussion of how that could have influenced CMS's reimbursement decisions. It cannot be inferred from the pleadings that CMS would have refused to reimburse Medicaid or Medicare claims for sleep studies if CMS officials knew that those studies were conducted using recalled Philips machines. Absent any logical link between the plaintiffs' efforts to replace recalled Philips machines and a potential false claim to CMS that would have been material to CMS's decision to pay for a sleep study, the court cannot find that it was objectively reasonable for the plaintiffs to believe that their efforts could have prevented

Abington from making a false claim to the federal government. Put differently, the plaintiffs' FCA retaliation claim fails to identify a nexus between the plaintiffs' conduct and a potential FCA violation.

Finally, Abington raises a causation argument, asserting that the nine-month gap between the plaintiffs' initial complaints about recalled machines in late June or early July 2021 and the plaintiffs' termination on March 31, 2022, was too broad for the two events to be causally linked. *See* Mot. to Dismiss 16-17. This argument is unpersuasive. The plaintiffs have alleged that they relayed their complaints to their direct supervisor for about eight months, until they finally went above their supervisor's head to complain to Dr. Friedenheim on March 4, 2022. The plaintiffs were then suspended less than a week after escalating their complaints, and they were fired just a few weeks after that. The likelihood that Abington's actions were pretextual is even higher if the plaintiffs have accurately stated that they enjoyed 15 or so years of employment at Abington without serious disciplinary incidents until the March 4th suspensions. Given these allegations, if the plaintiffs are able to amend the complaint to cure the issues outlined above, then Abington's causation argument would be more appropriately raised in a motion for summary judgment.

IV. CONCLUSION

It is very unfortunate that Mr. Hall and Mr. Carey were terminated after lengthy careers at Abington for what may have been minor infractions or what may have been retaliation against their protestations of the Sleep Center's continued use of recalled medical devices. But those issues are not properly before the court in the specific context of an FCA retaliation claim, because the plaintiffs have failed to plausibly allege that Abington's use of the recalled Philips machines *could have defrauded the federal government.* Therefore, the court grants Abington's motion to dismiss the FCA claim and declines to reach the plaintiffs' state law claims. The

complaint is dismissed without prejudice, and the plaintiffs may seek leave to amend the complaint as outlined in the order accompanying this memorandum.

BY THE COURT:

/s/ Kai N. Scott
HON. KAI N. SCOTT
United States District Court Judge